IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8883

Bartle, J. May 30, 2012

Dennis L. Eakle ("Mr. Eakle" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Janice L. Eakle, Mr. Eakle's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Allan P. Latcham, M.D., F.A.C.C. Dr. Latcham is no stranger to this litigation. According to the Trust, he has signed in excess of 138 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated July 1, 2002, Dr. Latcham attested in Part II of Mr. Eakle's Green Form that he suffered from moderate mitral regurgitation, an abnormal left atrial

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3. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension, and a reduced ejection fraction in the range of 50% to 60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $512,025.[5]

In the report of claimant's echocardiogram, Dr. Latcham noted that claimant had "moderate mitral valve regurgitation with the mitral valve area to left atrial area ratio of 30.35%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the regurgitant jet area ("RJA") in any apical view is greater than 20% of the left atrial area ("LAA"). See Settlement Agreement § I.22.

In November, 2005, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., one of its auditing cardiologists. In audit, Dr. Parmar determined that there was no reasonable medical basis for Dr. Latcham's finding that claimant had moderate mitral regurgitation because his echocardiogram

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4. Dr. Latcham also attested that claimant suffered from New York Heart Association Functional Class III symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

demonstrated only physiologic mitral regurgitation.[6] In support of this conclusion, Dr. Parmar explained that "[t]he [mitral regurgitation] is trace. The echo[cardiogram] tech[nician] has the color gain very high and as such the [mitral regurgitation] is over estimated. Also, the tech[nician] has over trace[d] the color by inclusion of low velocity flow. The tech[nician] has trace[d] color that is not representative of [mitral regurgitation]."

Based on the auditing cardiologist's finding that claimant had physiologic mitral regurgitation, the Trust issued a post-audit determination denying Mr. Eakle's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant argued that the auditing cardiologist's review of the echocardiogram was flawed. In support of this argument, claimant submitted a report from Waenard L. Miller, M.D.,

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6. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA."

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Eakle's claim.

F.A.C.C., who stated that Mr. Eakle had "moderate mitral regurgitation with RJA/LAA of 30%."

The Trust then issued a final post-audit determination, again denying Mr. Eakle's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Eakle's claim should be paid. On June 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6372 (June 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 31, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Mr. Eakle has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that she was unable to determine whether there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation due to improper machine settings. Specifically, Dr. Abramson observed that:

> In reviewing the transthoracic echocardiogram from 7/01/02, which was performed by FenPhen Limited Echo, the inappropriately high color gain settings make it difficult to assess the mitral regurgitation. The mitral regurgitant jet appears larger than it would if standard color gain settings had been used. It would be impossible for me to "guess" what the severity of the regurgitation would be if appropriate gain settings had been used. Gain settings are amplifications. Thus, it would be like listening to a song that is being played excruciatingly loud, and trying to decipher the melody despite its distortion.
>
> The technologist traced a mitral regurgitant jet on the tape that is frozen (not real time) and is much larger than any other jet seen on the tape. I am not confident that this is a representative jet.
>
> In summary, I am unable to assess the severity of this regurgitant jet due to the improper gain settings used in the acquisition of the study....

In a response to the Technical Advisor Report, claimant argues that because Dr. Abramson is unable to determine the severity of mitral regurgitation, and given Dr. Miller's qualifications, Dr. Miller's measured RJA/LAA ratio of 30% should be given deference.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not refute the determination of the Technical Advisor that "[t]he settings that were used in this [echocardiogram] are never used in a clinical setting. FenPhen Limited Echo performed this study using improper settings, which were used to make the regurgitant

jet appear larger than it would have if the correct settings had been used." On this basis alone, claimant has failed to meet his burden of demonstrating that there is a reasonable medical basis for his claim.

Moreover, we also disagree with claimant that Dr. Miller's letter establishes a reasonable medical basis for his claim. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Parmar and Dr. Abramson found that the echocardiogram used improperly high color gain settings. Dr. Parmar also determined that the supposed regurgitant jet included low velocity flow not representative of true mitral regurgitation. In addition, Dr. Abramson noted that the regurgitant jet frozen for measurement was not a representative jet, as it appeared much larger than the other

regurgitant jets seen in real time. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Mr. Eakle's claim for Matrix Benefits and the related derivative claim submitted by his spouse.